PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procanest 40 mg/ml + 0.036 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Procaine hydrochloride 40 mg
(equivalent to 34.65 mg procaine)
Adrenaline acid tartrate / Epinephrine acid tartrate 0.036 mg
(equivalent to 0.02 mg adrenaline / epinephrine)

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Sheep

5. INDICATIONS

-

6. ROUTES OF ADMINISTRATION

Subcutaneous and perineural use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Zero days
Milk: Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/4021

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml amber glass vial type II with bromobutyl rubber stopper and alu caps}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procanest 40 mg/ml + 0.036 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Procaine hydrochloride 40 mg
Adrenaline acid tartrate / Epinephrine acid tartrate 0.036 mg

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Subcutaneous, perineural.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Zero days
Milk: Zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

9. BATCH NUMBER

Lot {number}

100 ml

Commented [MW1]: The applicant kindly asks the pack size for additional information as per Article 13 of Regulation 2019/6, requested for all concerned member states.

Commented [AV2R1]: It is acceptable

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Procanest 40 mg/ml + 0.036 mg/ml solution for injection for sheep

2. Composition

Each ml contains:

Active substances:

Procaine hydrochloride (equivalent to 34.65 mg procaine)	40 mg
Adrenaline acid tartrate / Epinephrine acid tartrate (equivalent to 0.02 mg adrenaline / epinephrine)	0.036 mg

Excipients:

Sodium methyl parahydroxybenzoate (E219)	1.14 mg
Sodium metabisulfite (E223)	1 mg

Clear, colourless to almost colourless solution, free of visible particles.

3. Target species

Sheep

4. Indications for use

Local anaesthesia with an anaesthetic effect of 1 – 2 hours.

- Infiltration anaesthesia
- Perineural anaesthesia

5. Contraindications

Do not use in:

- conditions of shock
- in animals with cardiovascular diseases
- in animals under treatment with sulphonamides
- in animals treated with phenothiazines (see also section “Special warnings”)

Do not use in cases of hypersensitivity to local anaesthetics belonging to the esters subgroup or in case of possible allergic cross reactions to p-aminobenzoic acid and sulphonamides.
Do not administer by the intravenous or the intra-articular route.
Do not use to anaesthetise regions with terminal circulation (e.g. ears, tail, penis, etc.), owing to the risk of tissue necrosis following complete circulatory arrest, due to the presence of adrenaline (a vasoconstrictor).
Do not use with cyclopropane- or halothane-based anaesthetics (see also section "Special warnings").

6. Special warnings

Special warnings:
The local anaesthetic effect of procaine sets in after 5 to 10 minutes. Duration of effect of procaine itself is short (max. 30 to 60 minutes); with the addition of adrenaline to the solution, the duration of action is prolonged up to 90 – 120 minutes. The onset of anaesthetic effect is also dependent upon the target species and the age of the animal.

Special precautions for safe use in the target species:
Due to local tissue damage wounds or abscesses may be difficult to anaesthetise using local anaesthetics.
Perform local anaesthesia at ambient temperature. At higher temperatures, the risk of toxic reactions is higher owing to the greater absorption of procaine.
As with other local anaesthetics containing procaine, the veterinary medicinal product should be used with caution in animals with epilepsy, cardiac conduction disturbances, bradycardia, hypovolaemic shock or with changes in respiratory or renal function.
When injected near to wound edges, the veterinary medicinal product may lead to necrosis along the edges.
The veterinary medicinal product should be used with caution in lower limb blocks due to the risk of digital ischaemia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to adrenaline, procaine or other local anaesthetics of the ester group as well as derivatives of p-aminobenzoic acid and sulphonamides should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be irritant to the skin, eyes and oral mucosa. Avoid contact with the skin, eyes and oral mucosa. Wash any splashes immediately with plenty of water. Seek medical advice if irritation persists.
Accidental self-injection may result in cardiorespiratory and/or CNS effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Use only according to the benefit-risk

assessment by the responsible veterinarian during pregnancy, or lactation. Procaine crosses the placental barrier and is excreted in milk.

Interaction with other medicinal products and other forms of interaction:
Procaine inhibits the action of the sulphonamides owing to biotransformation to p-aminobenzoic acid, a sulphonamide antagonist. Procaine prolongs the effect of muscle relaxants. Procaine increases the action of antiarrhythmics, e.g. procainamide.
Adrenaline potentiates the action of analgesic anaesthetics on the heart.
Do not use with cyclopropane- or halothane-based anaesthetics, as they increase cardiac sensitivity to adrenaline (a sympathomimetic) and may cause arrhythmia.
Do not administer with other sympathomimetic agents as increased toxicity may result.
Hypertension may result if adrenaline is used with oxytocic agents.
An increased risk of arrhythmias may occur if adrenaline is used concomitantly with digitalis glycoside (as digoxin).
Certain antihistaminics (as chlorpheniramine) may potentiate the effects of adrenaline.
Due to these interactions, the veterinarian may adjust the dosage and should carefully monitor the effects on the animal.

Overdose:
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section “Adverse events”.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. The solution is incompatible with alkaline products, tannic acid or metal ions.

7. Adverse events

Sheep:
Common (1 to 10 animals / 100 animals treated):
Allergic reaction[1]

Rare (1 to 10 animals / 10 000 animals treated):
Anaphylaxis[2]

Undetermined frequency (cannot be estimated from the available data):
Hypotension[3], Tachycardia[4]; Agitation[5], Restlessness[6], Tremor[5,6], Convulsion[5,6], Depression[6], Death[6,7].

[1] To procaine. A hypersensitivity to local anaesthetics belonging to the esters subgroup is known. It should be treated with antihistamines or corticoids.
[2] Anaphylactic reactions have been observed in rare cases. Allergic shock should be treated with epinephrine.
[3] Due to procaine.
[4] In exceptional cases. Due to adrenaline.

[5] Particularly in horses, phenomena of excitability to the CNS are observed following the administration of procaine.
[6] Excitation of the central nervous system can occur in case of inadvertent intravascular injection. Short acting barbiturates should be administered, as well as products for acidification of urine, so as to support renal excretion.
[7] Due to respiratory paralysis.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous and perineural use.
For onset and duration of effect, please see section “Special warnings”

1. **Local anaesthesia or by infiltration**
   Inject into the subcutis or around the area involved.

   2.5 – 10 ml of the veterinary medicinal product/animal (i.e. 100 - 400 mg procaine hydrochloride + 0.09 - 0.36 mg adrenaline tartrate)

2. **Perineural anaesthesia**
   Inject close to the branch of the nerve.

   5 – 10 ml of the veterinary medicinal product/animal (i.e. 200 – 400 mg procaine hydrochloride + 0.18 - 0.36 mg adrenaline tartrate)

The rubber stopper can be punctured a maximum of 25 times.

9. Advice on correct administration

To avoid inadvertent intravenous administration, correct placement of the needle should be verified by aspiration.

10. Withdrawal periods

Sheep:
Meat and offal: Zero days.
Milk: Zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after “Exp”. The expiry date refers to the last day of that month.
Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.
Shelf life after first opening the immediate packaging: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 57446/4021

Package sizes

100 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
Tel: +43 (0)664 8455326
E-mail: adverse.events@vetviva.com

17. Other information

POM-V

Gavin Hall
Approved: 22 December 2025